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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,086	11/25/2003	Brian J. Lancaster	CRNI.111056	4915

46169 7590 10/26/2010

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EXAMINER	
LUBIN, VALERIE	
ART UNIT	**PAPER NUMBER**
3626	

MAIL DATE	DELIVERY MODE
10/26/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/720,086	LANCASTER ET AL.	
	Examiner	Art Unit	
	VALERIE LUBIN	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-15,17-25 and 35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-15,17-25 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/15/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/27/10 has been entered.

2. Claims 1-4, 6-15, 17-25, 35 are pending.

For reference purposes, the document paper number is 20101021.

Response to Amendments

3. The rejection of claims 12-15, and 17-22 under 35 U.S.C. 101 is withdrawn in light of Applicant's amendments.

4. The rejection of claims 29-34 under 35 U.S.C. 112, first paragraph and the rejection of claims 12-15 and 17-22 under 35 U.S.C. 112, second paragraph are withdrawn.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-4, 6-15, 17-22 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenfeld et al. U.S. Patent No. 6,804,656 in view of Shen Pre-Grant Pub No. 2003/0212580.

7. With regards to claim 1, Rosenfeld teaches a system comprising a first interface to a clinical data store (Col. 19 lines 2-44); a second interface to a knowledge base (Col. 5 lines 11-22; col. 22 lines 15-19); and an inference engine to selectively perform comparative analysis of the clinically related data against the knowledge base (Col 4. lines 8-13; col. 5 lines 11-22). Rosenfeld also recites key performance indicators (Col. 42 lines 11-43).

Rosenfeld does not specifically disclose that the comparative analysis projecting at least one facility-wide outcome based on an analysis of the clinically related data and a clinical guideline selected from the knowledge base, predicting an operational effect of altering a guideline or a policy being used in a clinical facility or organization; quantifying an opportunity for improvement if an altered guideline or policy is used in a clinical facility or organization, comparing result data from a control group that adheres to the altered guideline or policy and a non-control group that does not adhere to the altered guideline or policy,

wherein the result data includes one ore more of clinical and cost data for patients treated by the control group and the non-control group, and reassessing the at least one opportunity for improvement resulting from implementation of the altered guideline or policy in the clinical facility or organization based on the comparing of the result data. However, Shen does recite projecting at least one facility-wide outcome (¶ 133). Shen recites a facility-wide outcome and "simulation and prediction of modified process outcomes with new organizational goals; and dissemination of new policies/guideline/process through the organization" which is the equivalent of quantifying outcomes when altered policies or guidelines are implemented. Paragraph 123 discloses, "comparison of tests actually performed with tests guideline recommended to identify under utilization or over utilization…; comparing medical guidelines to the standard care given for quality improvement of services." Such a statement indicates that a comparison is being made between actual practices which would correspond to the group that does not adhere to the guidelines and recommended practices which corresponds to the group that does adhere to the guidelines. Paragraph 115 states, "Cost-benefit metrics track the final net revenues and compare them to a benchmark for further comparison to organizational goals to assess the potential future benefits." Paragraph 134 recites, "comparing different testing approaches and outcomes in specific patient population; and simulation of outcomes comparing with benchmarks or organizational projected goals with modification of current steps of processes." Those statements show that a reevaluation (e.g. comparing, simulation and modification) is done of outcomes (e.g. revenues, test performed) in order to improve towards benchmarks or organizational projected goals. It would have been obvious to one of ordinary skill in the art to combine the teachings of Rosenfeld with those of Shen in order to produced realistic projections.

Furthermore, Examiner notes that the language, "quantifying at least...when the altered…" is optional and according to the MPEP, “Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation.” MPEP 2106.II.C

8. Claim 12 is rejected under the analysis of claim 1, as Rosenfeld also recites generating an alert that notifies a user in the event that a guideline or threshold is violated (Col. 21 lines 45-47). Furthermore, the limitation is optional. Shen also recites determining a control group that adheres to guidelines, i.e. those that perform the guideline recommended tests (¶ 123); determining a non-control group that does not adhere to the guidelines; those that perform tests other than the recommended ones (¶ 123); comparing data from the control and non-control groups to identify a trend associated with implementation of the altered guideline or policy (¶ 123); and updating the comparative analysis by using the trend to project an updated facility-wide outcome (¶ 134 “such as analysis of historical data and trends using feedback and outcome to modify steps in the processes; monitoring and enhancing current process or redefining and reengineering new process”).

Claim 35 is rejected under the analysis of claims 1 and 12.

9. With respect 2, Rosenfeld teaches a data warehouse (Col. 7 lines 7-10).

Claim 13 is rejected under the analysis of claim 2.

10. Claim 3 is rejected as Rosenfeld teaches the data warehouse storing clinically related data from at least one clinical facility (Abstract; Fig. 8A item 9034; Fig. 8B item 9038).

Claims 4, 14 and 15 are rejected under the analysis of claim 3.

11. With respect to claim 5, Rosenfeld teaches the comparative analysis comprising an analysis of at least one key performance indicator (Col. 43 lines 11-53).

12. Claims 6 and 7 are rejected as Rosenfeld teaches the knowledge base comprising a set of clinical guidelines with best practices (Col 3. lines 51-55; col. 5 lines 11-22; col. 26 lines 8-17).

Claims 17, 18 are rejected under the analysis of claims 6 and 7.

13. For claim 8, Rosenfeld recites best practices data comprising pharmaceutical and medical procedure information (Col. 7 lines 24-67); and he discloses historical files (Col. 20 lines 42-46). Shen also recites the use of historical outcome information (¶ 134). It would have been obvious to one of ordinary skill to combine the teachings of Rosenfeld and Shen to include historical outcomes information in best practices for reuse when appropriate.

Claim 19 is rejected under the analysis of claim 8.

14. Claim 9 is rejected as Shen discloses the facility-wide outcome comprising a financial outcome, an operational outcome or a clinical outcome corresponding with a plurality of patients or a combination thereof (¶ 123). It would have been obvious to one of ordinary skill in the art to combine the teachings of Rosenfeld with those of Shen in order to produced realistic projections.

Claim 20 is rejected under the analysis of claim 9.

15. With respect to claim 10, Rosenfeld discloses maintaining a performance mortality measure (Col. 16 lines 4-6); and outcome algorithms for antibiotic cost information (Col. 7 line 31). Shen also recites clinical cost information (¶ 20, 112). A predictable result of Rosenfeld and Shen would be to include whatever information necessary (e.g. patient mortality and morbidity information, clinical cost information etc.) for informational purposes. (KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007)). Furthermore, the data contained in the outcome is non-functional descriptive material that does not further limit the process of claim 1 (In re Gulack, 217 USPQ 401 (Fed. Cir. 1983), In re Ngai, 70 USPQ2d (Fed. Cir. 2004), In re Lowry, 32 USPQ2d 1031 (Fed. Cir. 1994); MPEP 2106.01 II).

Claim 21 is rejected under the analysis of claim 10.

16. Claim 11 is rejected as Rosenfeld teaches storing the comparative analysis (col. 20 lines 1-5).

Claim 22 is rejected under the analysis of claim 11.

17. Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shen Pre-Grant Pub No. 2003/0212580 in view of Blechman Pre-Grant Pub No. 2003/0088434.

18. With respect to claim 23, Shen discloses a method comprising the steps of receiving a selection of one a plurality of policies and procedures stored within a knowledge base (¶ 20, 57, 85); accessing clinically related data corresponding with a plurality of patients (¶ 100); selectively performing comparative analysis of the clinically related data against the first

selected policy or procedure to provide an indication as to whether the first selected policy or procedure has been attained by a medical facility (¶ 100, 110). Furthermore, the language, "to provide an indication…" is directed to the intended result of the step of selectively performing a comparative analysis, and it has been held that a "clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited" (*Minton v. Nat'l Ass'n of Securities Dealers, Inc.*, 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003)). Examiner also notes that the type of clinically related data accessed does not further limit the method of claim 23

Shen also recites using selected policy or procedure and clinically related data corresponding with a plurality of patients to perform a predictive analysis that projects at least one operational, financial or facility-wide outcome (¶ 46,133); altering metrics, guidelines or policies (¶ 133, e.g. "simulation and prediction") with metrics relating to tests leading to a surgery (¶ 9, 72). Additionally, Shen recites a facility wide outcome and "simulation and prediction of modified process outcomes with new organizational goals; and dissemination of new policies/guideline/process through the organization" which is the equivalent of quantifying outcomes when altered policies or guidelines are implemented. Examiner notes that the quantifying step of the sixth limitation and subsequently, the seventh limitation of the claim are optional, and according to the MPEP, "Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation." MPEP 2106.II.C. Shen also recites the determining the impact of altered guidelines or policies on costs (¶ 20, 115, 134)

Shen does not specifically recite receiving a second selection of one of the plurality of policies; however, this is merely a duplication of the first limitation and it has been held that

the “mere duplication of parts has no patentable significance unless a new and unexpected result is produced” (In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960)).

Shen does not recite cataloging overrides of the altered selected guideline, policy or procedure by users; however, Blechman recites documenting the nature of overrides (¶ 96). It would have been obvious to one of ordinary skill in the art to add the features of Blechman to Shen with the motivation of using such documentation for analysis purposes.

19. Claim 24 is rejected, as Shen recites accessing a data warehouse (Abstract, ¶ 42).

20. Claim 25 is rejected, as Shen discloses performing an analysis of at least one key performance indicator (Abstract, ¶ 12).

Response to Arguments

21. Applicant's arguments filed 7/27/10 have been fully considered but they are not persuasive.

22. Applicant argues that the prior art does not teach "comparing results data from a control group and a non-control group or reassessing the opportunity for improvement resulting from implementation based on the comparison." Examiner respectfully disagrees and refers Applicant to Shen's paragraphs 123, 115 and 134. Paragraph 123 discloses, "comparison of tests actually performed with tests guideline recommended to identify under utilization or over utilization…; comparing medical guidelines to the standard care given for

quality improvement of services." Such a statement indicates that a comparison is being made between actual practices which would correspond to the group that does not adhere to the guidelines and recommended practices which corresponds to the group that does adhere to the guidelines. Paragraph 115 states, "Cost-benefit metrics track the final net revenues and compare them to a benchmark for further comparison to organizational goals to assess the potential future benefits." Paragraph 134 recites, "comparing different testing approaches and outcomes in specific patient population; and simulation of outcomes comparing with benchmarks or organizational projected goals with modification of current steps of processes." Those statements show that a reevaluation (e.g. comparing, simulation and modification) is done of outcomes (e.g. revenues, test performed) in order to improve towards benchmarks or organizational projected goals.

23. Applicant argues that Rosenfeld and She do not teach "data that has been processed to generate multidimensional extensions of the raw data." According to Applicant's description, "multidimensional data includes raw data that is enhanced to extend the data into logical structures reflecting meaningful groupings of the data not present in the raw data." Based on that definition, Examiner interprets Shen to recite such multidimensional data in ¶ 4 for example, "Collected data is correlated to at least one of the discrete steps in the model medical imaging process and process metrics for performance are calculated based upon the correlated data." In Shen, the collected data represent the raw data, and the medical imaging process and process metrics calculated from the correlated data represent the multidimensional data.

24. A new reference is introduced to teach Applicant's added limitation of cataloging overrides of the altered selected guideline, policy or procedure by users.

Conclusion

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE LUBIN whose telephone number is (571)270-5295. The examiner can normally be reached on Monday-Friday 7:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Morgan can be reached on 571-272-6773. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

26. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. L./
Examiner, Art Unit 3626

/Robert Morgan/
Supervisory Patent Examiner, Art Unit 3626